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EXAMINER
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3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/881,041	VONK ET AL.	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the amendment filed on 6/8/07. Claims 1-3, 5-8, 15-18, 20, and 23-24 have been amended. Claims 1-25 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Ballantyne et al.* (5,867,821; hereinafter *Ballantyne*), in view of *Joao* (6,283,761; hereinafter *Joao*), and in view of *Summerell et al.* (5,937,387; hereinafter *Summerell*).

(A) As per currently amended Claim 1, *Ballantyne* discloses a system for monitoring health-related conditions of patients, comprising:

(1) a plurality of remote monitoring stations, each being configured to receive patient health-related data pertaining to a respective patient (*Ballantyne*: col. 2, lines 25-26; Fig. 1-3); and

(2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (*Ballantyne*: abstract; col. 1, line 65-col. 2, line 63; col. 15, lines 56-65; Fig. 1-12 B).

Ballantyne, however, fails to *expressly* disclose a system for monitoring health-related conditions of patients, comprising:

(3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools; and

(4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient in response to said progress determination.

Nevertheless, these features are old and well known in the art, as evidenced by *Joao* and *Summerell*. In particular, *Joao* and *Summerell* disclose a system for monitoring health-related conditions of patients, comprising:

(3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions

concerning health or treatment that are generated using said electronic self-management tools (*Summerell*: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30); and

(4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient in response to said progress determination (*Joao*: abstract; col. 4, line 26-col. 5, line 54; col. 41, line 56-col. 43, line 29; Fig. 1-15B).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Joao* with the combined teachings of *Ballantyne* and *Summerell* with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Summerell* with the combined teachings of *Ballantyne* and *Joao* with the motivation of providing a system and method for healthcare (*Summerell*: col. 2, lines 56-59).

(B) As per currently amended claim 2, *Ballantyne* discloses a system as claimed in claim 1, wherein:

(1) each of said remote monitoring stations comprises at least one measuring device, configured to measure a physiological condition of said respective patient, and to provide data representative of said physiological condition for inclusion among said patient health-related data (*Ballantyne*: col. 11, lines 18-27).

Ballantyne, however, fails to *expressly* disclose a system as claimed in claim 1, wherein:

(2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.

Nevertheless, these features are old and well known in the art, as evidenced by *Summerell*. In particular, *Summerell* discloses a system as claimed in claim 1, wherein

(2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle

and determine readiness of the patient for self-management under the selected treatment program (*Summerell*: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Summerell* with the combined teachings of *Ballantyne* and *Joao* with the motivation of providing a system and method for healthcare (*Summerell*: col. 2, lines 56-59).

(C) As per currently amended claim 3, *Ballantyne* discloses a system as claimed in claim 1, wherein:

said remote monitoring stations are configured to provide said patient health-related data to said computer network over the Internet (*Ballantyne*: Fig. 1, 5, 7B)

(D) As per previously presented claim 4, *Ballantyne* fails to *expressly* disclose a system as claimed in claim 1, wherein:

(1) said electronic assessment tools are quality of life assessment tools (*Summerell*: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30) (Examiner has noted insofar as claim 4 recites "selected from the group consisting of Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific disease state

monitoring, depression scales, nutrition assessment tools, quality of life assessment tools," quality of life assessment tools is recited.).

Nevertheless, these features are old and well known in the art, as evidenced by *Summerell*. In particular, *Summerell* discloses a system as claimed in claim 1, wherein:

(1) said electronic assessment tools are quality of life assessment tools (*Summerell*: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Summerell* with the combined teachings of *Ballantyne* and *Joao* with the motivation of providing a system and method for healthcare (*Summerell*: col. 2, lines 56-59).

(E) As per currently amended claim 5, *Ballantyne* discloses a system as claimed in claim 1, wherein:

said computer network is configured to generate reports, each including health-related information pertaining to a respective said patient (*Ballantyne*: col. 15, lines 22-67; col. 16, lines 1-13).

(F) As per currently amended claim 6, *Ballantyne* fails to *expressly* disclose a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.

Nevertheless, these features are old and well known in the art, as evidenced by *Joao*. In particular, *Joao* discloses a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database (*Joao*: col. 4, lines 31-47; col. 37, lines 35-47; Fig. 1).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of *Joao* within the *Ballantyne* system with the motivation of facilitating the creation, management, quality, efficiency and effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

(G) As per currently amended claim 7, *Ballantyne* discloses a system as claimed in claim 1, wherein:

each said remote monitoring station receives from its respective said patient said patient health-related data including data pertaining to the cardiovascular system of said patient (*Ballantyne*: col. 11, lines 18-27).

4. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Ballantyne*, in view of *Joao*, and in view of *Seare et al.* (5,557,514; hereinafter *Seare*).

(A) As per currently amended claim 8, *Ballantyne* fails to *expressly* disclose a method for monitoring health-related conditions of patients, comprising:

(1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs;

(2) receiving economic data relating to protocols used in said treatment programs;

(3) aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and

(4) determining from said aggregated data recommendations for improving the treatment programs.

Nevertheless, these features are old and well known in the art, as evidenced by *Joao* and *Seare*. In particular, *Joao* and *Seare* disclose a method for monitoring health-related conditions of patients, comprising:

(1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs (*Joao*: abstract; col. 4, line 26-col. 5, line 54; Fig. 1-15B);

(2) receiving economic data relating to protocols used in said treatment programs (*Seare*: abstract; Fig. 1-15);

(3) aggregating said patient health-related data, said clinical data and said economic data with information comprising population outcomes and generic standards of care (*Seare*: abstract; Fig. 1-15); and

(4) determining from said aggregated data recommendations for improving the treatment programs (*Seare*: abstract; Fig. 1-15).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of *Ballantyne* and *Seare* with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Seare* with the combined teachings of *Ballantyne* and Joao with the motivation of assessing treatment programs (*Seare*: abstract).

The remainder of claim 8 substantially repeats the same limitations as those in claim 1 and therefore, the remainder of claim 8 is rejected for the same reasons given for claim 1 and incorporated herein.

(B) Claims 9-14 substantially repeat the same limitations as claims 2-7 and therefore, are rejected for the same reasons given for claims 2-7 and incorporated herein.

5. Claim 15-21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Ballantyne*, *Joao*, *Russek* (5,319,355; hereinafter *Russek*), and in view of *Soll et al.* (US 2003/0055679; hereinafter *Soll*).

(A) As per amended currently amended claim 15, *Ballantyne* discloses a method for managing health-related conditions of patients, comprising:

(1) collecting said healthcare data by using each said healthcare manager to collect respective patient health-related data for each respective patient in their said group of patients (*Ballantyne*: col. 2, lines 33-35; Fig. 11A-11D);

(2) controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each said patient in a database, said database further

including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes (*Ballantyne*: col. 12, lines 36-67 and col. 13, lines 1-18; Fig. 11A-11D); and

(3) updating said accumulated data in said database based on said health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (*Ballantyne*: col. 12, lines 33-35).

Ballantyne, however, fails to *expressly* disclose a method for managing health-related conditions of patients, comprising:

(4) assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients;

(5) coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment plan for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data;

(6) determining whether each respective patient is suitable for participation in a treatment program;

(7) wherein the determining step comprises the steps of:

(a) obtaining agreement from a respective patient to participate in a treatment program; and

(b) receiving approval from a payer who will pay for the treatment program;

(8) wherein the controlling step comprises the steps of:

(a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions; and

(b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient.

Nevertheless, these features are old and well known in the art, as evidenced by *Joao* and *Soll*. In particular, *Joao* and *Soll* disclose a method for managing health-related conditions of patients, comprising:

(4) assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients (*Russek*: col. 9, lines 29-32);

(5) coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment plan for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data (*Joao*: col. 4, lines 33-39 and col. 12, lines 22-43);

(6) determining whether each respective patient is suitable for participation in a treatment program (*Soll*: abstract; ¶ [0058]; Fig. 1-27);

(7) wherein the determining step comprises the steps of:

(a) obtaining agreement from a respective patient to participate in a treatment program (*Soll*: abstract; ¶ [0097]; Fig. 1-27); and

(b) receiving approval from a payer who will pay for the treatment program (*Joao*: abstract; col. 16, lines 38-65; Fig. 1-15B);

(8) wherein the controlling step comprises the steps of:

(a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions (*Joao*: abstract; col. 12, lines 43-50; col. 16, lines 38-65; Fig. 1-15B);

(b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient (*Soll*: abstract; ¶ [0058]; Fig. 1-27).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of *Ballantyne*, *Russek* and *Soll* with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

One having ordinary skill would have found it obvious at the time of the invention to combine the teachings of *Russek* with the combined teachings of *Ballantyne*, *Joao*, and *Soll* with the motivation of providing efficient and reliable communications concerning the medical conditions of patients (*Russek*: col. 3, lines 28-29).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Soll* with the combined teachings of *Ballantyne*, *Joao* and *Russek* with the motivation of providing a system and method of healthcare (*Soll*: ¶ [0014]).

(B) Claims 16-20 substantially repeat the same limitations as those in claims 1-7 and therefore, are rejected for the same reasons given for claims 1-7 and incorporated herein.

(C) As per previously presented claim 21, *Ballantyne* fails to *expressly* disclose a method as claimed in claim 15, wherein collecting healthcare data comprises said healthcare managers developing a client plan of care (CPOC) and a medical plan of

care (MPOC), the CPOC is developed during the interview with the patient, and the MPOC is developed with at least one member of the primary care team.

Nevertheless, these features are old and well known in the art, as evidenced by *Joao*. In particular, *Joao* discloses a method as claimed in claim 15, wherein collecting healthcare data comprises said healthcare managers developing a client plan of care (CPOC) and a medical plan of care (MPOC), the CPOC is developed during the interview with the patient, and the MPOC is developed with at least one member of the primary care team (*Joao*: col. 4, lines 40-47).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Joao* with the combined teachings of *Ballantyne*, *Russek* and *Soll* with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

(D) As per currently amended claim 23, *Ballantyne* discloses a method of establishing a treatment program for a patient comprising:

(1) collecting healthcare data by using said healthcare managers to collect respective <u>patient</u> health-related data for each of their assigned said patients (*Ballantyne*: col. 2, lines 33-35; Fig. 11A-11D); and

(2) controlling a computer network to receive said <u>patient</u> health-related data from each of said healthcare managers, and to store said <u>patient</u> health-related data pertaining to each of said patients in a database, said

database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes (*Ballantyne*: col. 12, lines 36-67 and col. 13, lines 1-18; Fig. 11A-11D);

Ballantyne, however, fails to *expressly* disclose a method of establishing a treatment program for a patient comprising:

(3) assigning healthcare managers to patients;

(4) determining whether each of said patients is suitable for participation in a treatment program;

(5) said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists;

(6) coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating members of the primary care team regarding the changes; and

(7) updating said accumulated data in said database based on said health-related data provided by said healthcare managers, including revisions to

the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions.

Nevertheless, these features are old and well known in the art, as evidenced by *Joao*, *Russek*, and *Soll*. In particular, *Joao*, *Russek*, and *Soll* disclose a method of establishing a treatment program for a patient comprising:

(3) assigning healthcare managers to patients (*Russek*: col. 9, lines 29-32);

(4) determining whether each of said patients is suitable for participation in a treatment program (*Soll*: abstract; ¶ [0058]; Fig. 1-27);

(5) said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists (*Joao*: col. 4, lines 40-47);

(6) coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating

members of the primary care team regarding the changes (*Joao*: col. 4, lines 33-39; col. 7, lines 43-48; col. 12, lines 22-43); and

(7) updating said accumulated data in said database based on said health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (*Joao*: col. 4, lines 33-39; col. 7, lines 43-48; col. 12, lines 22-43).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of *Ballantyne*, *Russek* and *Soll* with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

One having ordinary skill would have found it obvious at the time of the invention to combine the teachings of *Russek* with the combined teachings of *Ballantyne*, *Joao*, and *Soll* with the motivation of providing efficient and reliable communications concerning the medical conditions of patients (*Russek*: col. 3, lines 28-29).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Soll* with the combined teachings of *Ballantyne*, *Joao* and *Russek* with the motivation of providing a system and method of healthcare (*Soll*: ¶ [0014]).

(E) As per currently amended claim 24, *Ballantyne* fails to *expressly* disclose a method as claimed in claim 23 further comprising:

(1) scheduling conferences between said patients and said members of the primary care team; and

(2) documenting patient-related communications comprising at least one of messages, an interview communication and conference communication during the conference and during non-scheduled patient-related communications for storage in said database.

Nevertheless, these features are old and well known in the art, as evidenced by *Joao*. In particular, *Joao* discloses a method as claimed in claim 23 further comprising:

(1) scheduling conferences between said patients and said members of the primary care team (*Joao*: col. 4, lines 54-55); and

(2) documenting patient-related communications comprising at least one of messages, an interview communication and conference communication during the conference and during non-scheduled patient-related communications for storage in said database (*Joao*: col. 16, lines 38-65).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of *Joao* with the combined teachings of *Ballantyne*,

Russek and *Soll* with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

(F) As per previously presented claim 25, *Ballantyne* fails to *expressly* disclose a method as claimed in claim 23 further comprising:

(1) said healthcare managers following clinical encounter schedules to communicate with their said patients;

(2) using scripts to communicate with said patients during the clinical encounters; and

(3) assessing said patients' physical and psychological responses.

Nevertheless, these features are old and well known, as evidenced by *Joao*. In particular, *Joao* discloses a method as claimed in claim 23 further comprising:

(1) said healthcare managers following clinical encounter schedules to communicate with their said patients (*Joao*: col. 4, lines 54-55);

(2) using scripts to communicate with said patients during the clinical encounters (*Joao*: col. 19, lines 59-64); and

(3) assessing said patients' physical and psychological responses (*Joao*: col. 16, lines 38-65; Examiner also notes that *Joao* incorporates U.S. Pat. No.

5,961,332 by reference that teaches assessing psychological responses as well. See *Joao*: col. 12, lines 48-50.).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of *Ballantyne*, *Russek* and *Soll* with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (*Joao*: col. 2, lines 38-54).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Ballantyne*, *Joao*, *Russek*, in view of *Soll*, and in view of *Official Notice*.

(A) As per previously presented claim 22, *Ballantyne* fails to *expressly* disclose a method as claimed in claim 15, wherein the determining comprises excluding a respective patient based on selected criteria comprising the patient is a minor, the patient has not received a selected diagnosis, and the patient cannot communicate effectively, and including a respective patient based on selected criteria comprising having a selected primary diagnosis and being at risk for future hospital admissions.

Nevertheless, Examiner takes *Official Notice* of the technique of "excluding" patients from treatment programs based on various criteria such as those claimed by Applicant. For example, it is well established that minors are often excluded from certain healthcare treatment plans, such as abortions, cosmetic surgeries, and the like.

Similarly, Examiner also takes *Official Notice* of the technique of "including" a patient based on various criteria such as those claimed by Applicant. For example, physicians routinely subject a patient to a diagnosis and then formulate a treatment plan based on the primary diagnosis of the patient. As such, Examiner respectfully submits that the features of claim 22 are old and notoriously well known. Moreover, Examiner submits that these features were developed and widely used well prior to Applicant's claimed invention.

Response to Arguments

7. Applicant's arguments filed 6/8/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 6/8/07.

(A) On pages 14-15 of the 6/8/07 response, Applicant argues that *Ballantyne* merely refers to the storage of patient medical health records and not to accumulated data relating to population trends and outcomes, nor revision of this data to identify improvements of standards of care and medical practices.

In response, Examiner disagrees and respectfully submits that a broad, yet reasonable interpretation of Applicant's claim language reads on the teachings of *Ballantyne*, as cited in section 3. (A), *supra*. That is, patient medical records (i.e., health-related data pertaining to conditions and treatment) do ***reveal*** various

information, including, but not limited to, population trends and outcomes. As per *Summerell* and *Joao*, Examiner did not specifically rely on these references to address the aforementioned features.

(B) On page 15 of the 6/8/07 response, Applicant argues that *Summerell* does not disclose an electronic self-management tool that allows a patient to integrate a health care provider's established treatment program, rather, *Summerell* seeks to provide a tool for users to select their own wellness plan without involvement of a health care provider.

In response, Examiner disagrees with Applicant's interpretation of *Summerell* and notes that *Summerell* ***does*** provide a tool for users to select their own wellness plan ***with*** involvement of a health care provider. For example, the *Summerell* system incorporates patient questionnaires and plan recommendations created by a doctor (*Summerell*: Figure 2). Further, *Summerell* teaches establishing a dialogue between patient and doctor (*Summerell*: col. 4, lines 15-19). Finally, Examiner respectfully submits that the *Summerell* system itself can be broadly construed to read on "health care provider."

(C) On pages 15-16 of the 6/8/07 response, Applicant argues that *Joao* does not teach electronic assessment tools to allow a health care provider to determine whether information relating to a selected treatment program needs to be conveyed to the patient in response to progress determination, as recited in amended claim 1.

In response, Examiner notes that *Joao* does disclose a computer network configured with electronic assessment tools (See section 3. (A), *supra*). As per allowing a health care provider to determine whether information relating to a selected treatment program needs to be conveyed to the patient in response to progress determination, Examiner maintains that this claim language is intended use.

(D) On page 16 of the 6/8/07 response, Applicant argues that *Summerell* teaches away from combined teachings of *Ballantyne* and *Joao*.

In response, Examiner notes that this argument was addressed in the previous Office Action filed 1/8/07. Examiner also notes, as Applicant points out, that Examiner did not apply the *Soll* reference to claims 1-7, rather Examiner applied *Ballantyne*, *Joao* and *Summerell* to claims 1-7.

(E) On page 17 of the 6/8/07 response, Applicant argues that even if *Joao* could arguably be interpreted as disclosing selection of a treatment program and determination that a treatment/procedure is performed in the patient, the disclosed evaluation report is transmitted to the payer and not to the patient.

In response, Examiner notes that *Joao* teaches "any patient, user, provider, payer, and/or intermediary, may utilize the present invention in the same, similar and/or analogous manner." As such, *Joao* teaches that the evaluation report can be transmitted to any entity (e.g., payer, patient, etc.).

(F) On pages 17-18 of the 6/8/07 response, Applicant essentially asserts that Examiner erroneously applied Form Paragraph 7.37.09 Unpersuasive Argument: Intended Use for the following reasons: 1) claim 1 recites, in the claim body, claim limitations argued to be distinguished and nonobvious over the applied references; 2) Examiner applied only a partial quotation of Form Paragraph 7.37.09; and 3) intended use only applies to claim recitations in the preamble.

In response, Examiner respectfully disagrees with Applicant's assessment on all three counts.

First, Applicant argues that claim 1 recites limitations argued to be distinguished and nonobvious over the applied references. Examiner, however, notes that there are ***no structural differences*** between the claimed invention and the prior art to patently distinguish the claimed invention form the prior art. As such, Examiner reiterates that if the prior art structure is capable of performing the intended use, then it meets the claim.

Second, Applicant argues Examiner applied only a partial quotation of Form Paragraph 7.37.09. In response, Examiner notes that Examiner has applied Form Paragraph 7.37.09 verbatim, as provided by the most recent edition of the MPEP (MPEP: ch. 7, p. 156.).

Third, Applicant argues that intended use only applies to claim recitations in the preamble. In response, Examiner respectfully disagrees and notes that the MPEP provides two form paragraphs for intended use, a general form paragraph for addressing intended use limitations throughout a claim and a specific intended use

paragraph for limitation(s) recited in a preamble, form paragraphs 7.37.09 and 7.37.10, respectively.

Furthermore, assuming *arguendo* that Applicant's assertion is valid, the preamble of claim 1 recites "A system for monitoring health-related conditions of patients, comprising:" and incorporates no structural differences over the prior art. As such, Examiner respectfully submits that the intended use rejection is appropriate.

(G) On pages 24-25 of the 6/8/07 response, Applicant essentially argues that the Examiner erroneously applied *Official Notice* to claim 22.

In response, Examiner notes that in order to adequately traverse an *Official Notice* finding, an Applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art [Emphasis added]. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241 ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention.").

Moreover, if Applicant does not traverse the Examiner's assertion of *Official Notice* or Applicant's traverse is not adequate, the Examiner should clearly indicate in the next *Office Action* that the common knowledge or well-known in the art statement is taken to be admitted prior art because Applicant either failed to traverse the Examiner's assertion of *Official Notice* or that the traverse was inadequate. If the traverse was inadequate, the Examiner should include an explanation as to why it was inadequate.

Accordingly, Examiner respectfully submits that Applicant's traverse of *Official Notice* was inadequate because Applicant did not state why the noticed fact is not considered to be common knowledge or well-known in the art. As such, the features rejected via *Official Notice* are deemed to be admitted prior art.

(H) Applicant's remaining arguments within the 6/8/07 response rely upon or re-hash the issues addressed above and/or in previous Office Actions. Therefore, these arguments are moot in view of the responses given in §§ 7. (A) – (G), *supra,* and previous Office Actions.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MT

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